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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,564	02/05/2002	Emad S. Alnemri	480140.434C2	8175

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EXAMINER

NICKOL, GARY B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/068,564	Applicant(s) ALNEMRI ET AL.	
	Examiner Gary B. Nickol Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2004.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 56-60,69 and 70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 56-60,69 and 70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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Re: Alnemri *et al.*

Date of priority: 11/06/1998

***Response to Amendment***

The Response filed 09-28-2004 in response to the Office Action of 07-20-2004 is acknowledged and has been entered.

Claims 56-60, and 69-70 are currently under consideration.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

***Terminal Disclaimer***

The terminal disclaimer filed on 09-28-2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application No. 09/989,903 has been reviewed and is accepted. The terminal disclaimer has been recorded.

**Rejection Maintained:**

Claims 56-60, and 69-70 (Claim 70 was inadvertently omitted from the previous Action but is now included herein.) are rejected under 35 U.S.C. 103(a) as being unpatentable over

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Rasmussen *et al.* (Electrophoresis, Vol. 13, pages 960-969, 1992) for the reasons of record and for the reasons set forth below:

Applicants argue (Response, page 4) that the polypeptide sequence described by Rasmussen *et al.* is not a caspase-14 polypeptide comprising SEQ ID NO:5. Thus, any antibodies produced against the polypeptide of the prior art would not be specific for a caspase-14 polypeptide comprising SEQ ID NO:5. This argument has been considered but is not found persuasive. With nearly 100% identity (99.6%) sequence similarity, it is noted that both the prior art polypeptide and SEQ ID NO:5 comprise the same number of amino acids residues (242) with only one mismatch between them. In the instant case, it is irrelevant that both polypeptides are not exactly the same because, as set forth previously, antibodies specific for the prior art polypeptide would also bind to the caspase-14 polypeptide comprising SEQ ID NO:5.

Applicants further argue (Response, page 4) that assuming Rasmussen *et al.* taught each element of the claimed invention, the reference fails to render the claimed invention obvious because it does not provide the requisite teaching or suggestion of the desirability of the invention. Here, applicants argue that the prior art “must suggest the desirability of the combination”. This argument has been considered but is not found persuasive. The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (setting forth test for implicit

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teachings); In re Eli Lilly & Co., 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); In re Nilssen, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings); Ex parte Clapp, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985) (examiner must present convincing line of reasoning supporting rejection); and Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (reliance on logic and sound scientific reasoning). In the instant case, the production of antibodies from an isolated polypeptide was based on established scientific principles. Moreover, legal precedent established by prior case law supports the production of antibodies. The Board of Patent Appeals and interferences has taken the position that once an antigen has been isolated, the manufacture of monoclonal antibodies against it is *prima facie* obvious. See Ex parte Ehrlich, 3 USPQ 2d 1011 (PTO Bd. Pat. APP. & Int. 1987), Ex parte Sugimoto, 14 USPQ 2d 1312 (PTO Bd. Pat. App. & Int. 1990). Hence, claim 70 is also obvious because it is conventional in the art to use cell hybridomas in order to express and isolate monoclonal antibodies. Applicants further appear to argue (Response page 5) that a description of multiple polypeptides in the prior art would not suggest nor motivate one of ordinary skill in the art to produce antibodies to any one particular polypeptide, including those similar to the claimed invention. This argument has been carefully considered but is not found persuasive, because according to applicant's logic, this reasoning would apply to not making antibodies against any of the polypeptides disclosed in the prior art. Thus, the number of polypeptides described in the prior art does not teach away from manufacturing antibodies to any one of the described polypeptides. Further, a clear objective for producing antibodies against a described polypeptide is not necessary as it is conventional in the art to generate antibodies following the cloning of a gene. Campbell, A.M., ("Monoclonal

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Antibody Technology"; Laboratory Techniques in Biochemistry and Molecular Biology, Vol. 13, pages 1-32, 1984) teaches (page 29) that it is "customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)". Thus, applicant's arguments have not been found persuasive, and the rejection is maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.

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Primary Examiner  
Art Unit 1642

GBN

A handwritten signature in black ink, appearing to read "Gary Nickol". The signature is written in a cursive, flowing style with a large initial "G" and a long, sweeping underline.

**GARY NICKOL**  
**PRIMARY EXAMINER**